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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR               | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/599,497      | 09/29/2006  | Peter Jan Leonard Mario Quaedflieg | TIP-0060USPCT       | 9839             |

27777 7590 07/09/2008  
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| EXAMINER |
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CHANDRAKUMAR, NIZAL S

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| ART UNIT | PAPER NUMBER |
|----------|--------------|

1625

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|-------------------|---------------|
| NOTIFICATION DATE | DELIVERY MODE |
|-------------------|---------------|

07/09/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jnjuspatent@corus.jnj.com

|                              |  |  |  |
|------------------------------|--|--|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/599,497     | <b>Applicant(s)</b><br>QUAEDFLIEG ET AL. |  |
|                              | <b>Examiner</b><br>NIZAL S. CHANDRAKUMAR | <b>Art Unit</b><br>1625                  |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 May 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

Art Unit: 1625

### **DETAILED ACTION**

This application filed 09/29/2006 is a 371 of PCT/EP05/51452 03/31/2005.

Claims 1-26 are before the Examiner.

### ***Election/Restrictions***

Applicants response filed 05/28/2008. In accordance with applicants Remarks, the previously presented rejection is vacated. Presently amended claims filed 05/28/2008 is examined.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 2 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 and 2 provides for the use of intermediate (4), but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 1 and 2 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claims 23-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite 'intermediate' without distinctly stating what these intermediates are for.

Art Unit: 1625

Claims 23 and 25 are duplicates.

### ***Claim Rejections - 35 USC § 103***

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-26 rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kesteley et al. US ~~7,260,151~~ B2 (Priority to PCT/EP/0210062 filing date 09/16/2002, publication date 03/20/2003).

### **Instant claims**

The claims are drawn to processes and intermediates for the preparation of (3R,3aS,6aR) HEXAHYDRO-FURO[2,3-b]FURAN-3-OL

### **Prior art**

Kesteley et al. teach processes and intermediates for the preparation of (3R,3aS,6aR) HEXAHYDRO-FURO[2,3-b]FURAN-3-OL, in which the R2 of  $\alpha$ ,  $\beta$ -unsaturated ester intermediate as well as in the nitro-compound structure of claim 1 is H.

### **Difference**

The process of Kesteley et al. is identical to the instantly claimed process, except the disclosure of Kesteley et al., teaches the instant process (R2 = H) as well as innocuous substituent (R2 carboxylic ester) that is not material to the overall reaction process. Further in the instant process some intermediates are crystallized/purified prior to subsequent steps. Likewise, minor variations such as reaction temperature, are also not identical in the two processes.

Art Unit: 1625

**Motivation and Rationale**

One of ordinary skill in the art trying to identify alternate process for making (3R,3aS,6aR) HEXAHYDRO-FURO[2,3-b]FURAN-3-OL would be motivated to modify Kesteley et al. processes as a matter of routine process optimization protocol. It would have been obvious to obtain known product(s) using analogues reagents and alternate conditions in lieu of another as the results would have been obvious. For example, the instantly claimed separation of anomeric methoxy compounds (formula 4) by crystallization is inconsequential because one skilled in the art would know the mechanistic reasons underlying the intramolecular cyclization, that is the obligatory formation of oxonium ion intermediate. Example 8, on page 47 of the specification refers to the prior art method for the cyclization but no unexpected results, such as improvement in the yield, is disclosed.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Kesteley et al.

US ~~72016~~ B2. (Priority to PCT/EP/0210062 filing date 09/16/2002, publication date 03/20/2003).

The process of the prior art wherein the R2 is H is the same as the process of the instant case claims 1-22. The isomerically pure intermediates of the instant claims 23-26 are inherently present in the disclosure of the prior art wherein anomeric mixtures are claimed.

Art Unit: 1625

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NIZAL S. CHANDRAKUMAR whose telephone number is (571)272-6202.

The examiner can normally be reached on 8.30 AM - 4.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571 0272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nizal S. Chandrakumar

/D. Margaret Seaman/  
Primary Examiner, Art Unit 1625